UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

CITIZENS FOR CONSUMER JUSTICE, COLORADO PROGRESSIVE COALITION,))
FLORIDA ALLIANCE FOR RETIRED AMERICANS, HEALTH CARE FOR ALL, INC., MASSACHUSETTS SENIOR ACTION COUNCIL, MASSPIRG, MINNESOTA SENIOR FEDERATION, NEW JERSEY CITIZEN ACTION, NEW YORK STATE WIDE SENIOR ACTION COUNCIL, PENNSYLVANIA ALLIANCE FOR RETIRED AMERICANS, VERMONT PUBLICE INTEREST RESEARCH GROUP, WEST VIRIGINA CITIZEN ACTION, AND WISCONSIN CITIZEN ACTION,	Case No. 01-12257 PBS Case No. 01-12257 PBS
Plaintiffs,))
v.	
ABBOTT LABORATORIES, INC., ALLERGAN WORLDWIDE, ALPHA TERAPEUTIC CORP., AMERICAN BIOSCIENCE, INC., AMERICAN HOME PRODUCTS, AMGEN, INC., ASTRAZENECA US, AVENTIS PHARMA, BAYER AG, BAXTER INTERNATIONAL, INC., BRITSOL-MYERS SQUIBB CO., CHIRON, FUGISAWA HEALTHCARE, INC. GLAXOSMITHKLINE, PLC, GENSIA SICOR PHARMACEUTICALS, INC., GLAXO WELLCOME, INC., GLAXO WELLCOME, INC., GLAXO WELLCOME, INC., HOESCHT MARION ROUSSEL, INC., ELI LILLY AND COMPANY, ONCOLOGY THERPEUTICS NETWORK CORP., PHARMACIA CORP., SCHERING-PLOUGH, CORP., SICOR, INC., SMITHKLINE BEECHAM CORPORATION, TEKEDA CHEMCIAL INDUSTRIES LTD., TAP PHARMACEUTICAL PRODUCTS, INC., AND JOHN DOES 1 – 200	
Defendants	,))

AFFIDAVIT OF DANIEL M. CONCAUGH

DANIEL CONCAUGH, being duly sworn, hereby states as follows:

- I am employed by Fallon Community Health Plan (hereinafter "FCHP") as the Vice President of Network Development and Management, a position I have held since 2000. (I have worked for FCHP since 1998.) My responsibilities in this position include, but are not limited to, working with state and federal regulatory agencies to ensure FCHP's compliance with federal and states rules, regulations and procedures, and ensuring that FCHP maintains its health care certifications which are granted by the National Commission on Quality Assurance.
- 2. FCHP is a health maintenance organization which was incorporated in May 1975. Since its inception, FCHP has provided health insurance to employer groups and individuals whereby members can receive benefits including, but not limited to, pharmaceuticals and physician care. FCHP serves a total of approximately 171,000 members in 228 cities and towns, primarily located in Worcester County. By contrast, I believe that FCHP's major competitors, Blue Cross/Blue Shield and Harvard Pilgrim Health Care, serve over 2,400,000 and 800,000 members, respectively.
- 3. FCHP employs a total of approximately 525 employees. Of that total, approximately 200 serve in an administrative capacity that would be involved in responding to document production requests served upon FCHP in litigation.
- 4. I am familiar with and have reviewed the Document Production Request served by Dey, Inc.

Document Request Number One

- 5. In order to comply with the first document production request, which seeks in part "all schedules disclosing the amount reimbursed to physicians for services rendered and drugs administered ... and documents detailing how those schedules were calculated," 1 FCHP would need to review approximately one hundred to one hundred twenty thousand separate contracts. (There were approximately 8,000 contracts executed yearly from 1991 through the present between FCHP and individual physicians, entities that employed physicians, and/or providers.) Each of these contracts is five to thirty pages in length. There is no computer records search available to access these contracts in a way that will provide the information sought. Thus, each contract will have to be manually examined to obtain the information (if it exists), and to redact commercially sensitive and proprietary information (such as the specific reimbursement amounts paid to physicians, from which our competitors could calculate our fee schedule methodology, to our detriment). The contract review would also entail a manual process to identify the drugs which were on the formulary, and the reimbursable amounts. It is estimated that it will take 50,000 hours to conduct this review.
- 6. FCHP maintains approximately three years of records at its Chestnut Street administrative offices; older records are stored at an Iron Mountain commercial storage facility. The facility charges a cost for retrieving and then re-storing the records. Thus, retrieving these particular records (approximately eleven years'

¹ This document request states in its entirety as follows: "All schedules disclosing the amounts reimbursed to physicians for services rendered and drugs administered (i.e., physician "fee schedules") and documents detailing how those schedules were calculated or derived. To the extent the fee schedules differ from the electronic schedules or tables used to generate the actual reimbursement amounts paid to physicians, produce all such schedules and tables."

worth), and then establishing a warehouse where they can be stored and searched during the period of review, would impose a significant (though as yet undetermined) out-of-pocket expense on FCHP, in addition to the internal labor cost of the review. Further, the records are not catalogued in a way that corresponds to the Requests, but rather by FCHP department; accordingly, the retrieval and review process would be much broader in scope than merely requesting specified records.

Document Request Number Two

- A similar process would have to be followed to procure the electronic medical claims data sought in the second document production request, which seeks to learn how FCHP reimbursed providers for one hundred and ten different drugs and seeks all data for related administration or service fees.² Electronic medical data is submitted to FCHP's Claims Department directly by physicians. There are tens of thousands of electronic medical claims submitted on a daily basis. FCHP does not have a computer records search engine that could identify the sought-after information. Each electronic medical claim will therefore have to be manually reviewed in order to determine if it is subject to this request. If FCHP must follow this procedure, it would require the review of millions of claims records for each year from 1991 to present. I estimate it will take tens of thousands of hours to complete this request.
- 8. As with the documents sought in the first request, producing this data would subject FCHP to a high degree of commercial risk, as the data sought would allow a competitor to calculate FCHP's fee and reimbursement schedules. FCHP considers

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² This document request states in its entirety as follows: "Electronic medical claims data regarding reimbursement to Providers for all drugs on the list attached hereto as Exhibit A, including all data regarding reimbursements for related administration or service fees, and all claims processing manuals corresponding to the electronic medical claims data produced."

- that information its most proprietary and sensitive trade secret, and maintains multiple means of protecting its confidentiality.
- 9. The request also seeks claims processing manuals. Portions of these are also proprietary because they reveal FCHP's internal procedures for handling claims. Further, FCHP does not maintain a specific file of these manuals for all the years in question, and FCHP would have to retrieve an unknown number of records from its off-site storage to comply with this request.

Document Request Number Four

10. It would be burdensome to comply with this request, which seeks in part all documents concerning advisory boards involving pharmacies and physicians conducted by FCHP since 1991.³ FCHP advisory boards (or similar committees) include Customer Service; Utilization Management; Physician Advisory Committee; and Pharmacy and Therapeutic. Generally these committees meet either quarterly or monthly. The Affidavit of Dr. Leslie Fish addresses what would be involved in obtaining, reviewing, and producing the requested Pharmacy and Therapeutic records. With regards to the remaining committees, agendas and meetings notes are generated by each, which are not searchable by a computer records search. Thus, these records will have to be manually examined. On an annual basis, thousands of pages are produced by these committees, and it will take hundreds of hours to conduct this review.

³ This request states in its entirety: "All documents concerning advisory boards conducted by You, or on Your behalf, involving physicians or pharmacists, including final reports or other documents reflecting the issues discussed, documents reflecting all entities participating in such advisory boards, and documents reflecting the conclusions of such advisory boards."

Document Request Number 8(a)

11. The documents sought by this request⁴ conceivably include every document maintained by FCHP. Among others, fee schedules, contracts and amendments, licenses, claims, appeals, referrals, formulary approvals and denials, would all seem to qualify as responsive to the subpoena. As a result, it would be extraordinarily burdensome to attempt to comply, and potentially would result in the disclosure of proprietary information.

Other Information Relevant to the Burden on FCHP of Responding to the Requests

- 12. FCHP has a five year contract with Medicaid that expires in June 2006. FCHP anticipates renewing that contract, and is currently preparing for a site visit from Medicaid which must take place before that can be accomplished. FCHP may receive a Request for Information ("RFI") from Medicaid in advance of that site visit, which must be completed approximately three months after receipt. Compliance with the RFI requires FCHP to produce these documents in support of its application in advance of the site visit.
- 13. Additionally, FCHP is presently participating in an annual inspection from the Massachusetts State Division of Insurance, and preparing its annual DOI Annual Statement Filing. Many FCHP employees who would otherwise be available to help with complying with the document request are already working up to 80 hours per week in order to meet the regulatory requirements of these requirements, and will not be freed from those duties until March, 2006.

⁴ "All documents, including communications between You and Providers, regarding: (a) The cost to Providers of acquiring physician-administered drugs, including, but not limited to, the drugs on the list attached hereto..."

- 14. Further, as a 501(c)(3) entity, FCHP undergoes a two-week annual audit by its financial auditors in anticipation of its filings with the Commonwealth of Massachusetts. That audit is conducted by Ernst and Young; takes place in February of each year; and consumes an estimated 40 hours/week of FCHP staff time while the auditors are present on-site.
- 15. Finally, a significant portion of the documents discussed herein contain private medical records. As an entity with access to such records, FCHP must be sensitive to the requirements of the Health Insurance Portability and Accountability Act ("HIPAA"), which mandates confidentiality of such records except under certain specified conditions. FCHP currently has two staff positions devoted exclusively to HIPAA compliance; the daily compliance with HIPAA terms and conditions by other FCHP staff consumes the Full Time Equivalent of an estimated 10 more positions. Review of the records in anticipation of disclosure pursuant to the subpoena will entail a separate, additional analysis by legal counsel, as it exceeds the scope of analysis conducted by existing staff.

Conclusion

16. In short, compliance with the document requests at the present time will impose extraordinary and, indeed, near-impossible burdens on FCHP regarding staff time, legal time, and out-of-pocket expense.

FURTHER, THE AFFIANT SAYETH NAUGHT.

Signed under the pains and penalties of perjury this Abk day of January 2006.

Daniel M. Concaugh

STATE OF MASSACHUSETTS

WORCESTER COUNTY

On this 26th day of January 2006, before me, the undersigned Notary Public, personally appeared Daniel M. Concaugh, in his individual capacity, known to me (or satisfactorily proven) to be the person whose name is subscribed to the foregoing instrument, and acknowledged that he signed the same as his voluntary act and deed for the purposes therein contained

Notary Public

My Commission Expires: 5/5/20//

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